IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Lennox Hoyte, M.D.)

The defendant C.R. Bard, Inc. ("Bard") filed its Notice of Adoption of Motion to Exclude or Limit Certain Opinions and Testimony by Lennox Hoyte, M.D. in Wave 4 and 5 cases ("Notice") [ECF No. 4569] in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, on September 28, 2017. The defendant attached as exhibits to its Notice a motion [ECF No. 4569-2] and memorandum in support [ECF No. 4569-3], which the defendant seeks to adopt and incorporate as its briefing for Waves 4 and 5. Plaintiffs also adopted and incorporated by Notice of Adoption of Prior Daubert Response of Lennox Hoyte, M.D. for Waves 4 and 5 Cases, a brief in response to Defendant's Motion. [ECF No. 4596]. The court construes the defendant's Notice as a Motion. As such, the Notice is now ripe for consideration because the briefing is complete. As set forth below, Bard's motion is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses, and replies were to be filed in the individual member cases. To the extent that an

expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in the individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

Before plunging into the heart of the motion, and to clarify the record, I am compelled to comment on the manner in which the parties filed the instant *Daubert* motion and opposition. Similar to other *Dauberts* filed in the main MDL, Bard filed the instant motion as a "Notice" adopting and incorporating the entirety of a motion and its corresponding papers filed in a previous case before the court. The plaintiffs, likewise, filed their opposing briefs in conjunction with a "Notice." The parties then attached the substance of their briefs, i.e., the supporting or opposing memorandum of law, as an exhibit to the Notice. So, for example, Bard's *Daubert* motion is attached as Exhibit B to the Notice. Exhibit B also integrates vital supporting papers into one large document, such as the expert report or deposition transcripts, demarcated rather confusingly within Exhibit B as "Exhibit A" and "Exhibit B" respectfully. With this in mind, the court turns its attention to the present dispute.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence

is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of

error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted). At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

The plaintiffs offer Dr. Lennox Hoyte, a urogynecologist board-certified in Female Pelvic Medicine and Reconstructive Surgery, to testify on a number of general causation issues, including the characteristics of polypropylene and product design. Bard takes issues with these opinions and objects to certain other statements advanced by Dr. Hoyte, arguing that he is unqualified to render these opinions or that his methodology is not reliable under *Daubert*.

A. Opinions on the Characteristics of Polypropylene

First, Bard argues that Dr. Hoyte is not qualified to opine on the characteristics and behavior of polypropylene because he has never studied or trained in polypropylene or biomaterials. *See* Notice of Adoption of Prior Daubert Mot. to Exclude or Limit Certain Ops. & Test. by Lennox Hoyte, M.D., in Wave 4 & Wave 5 Cases, Ex. C ("Bard's Mem. in Supp."), at 3-4 [ECF No. 4569-3]. He is not an epidemiologist, a microbiologist, a bacteriologist, or a pathologist, Bard continues. In short, Bard contends that Dr. Hoyte relies only on his general experience as a urogynecologist, which Bard contends is insufficient, arguing that Dr. Hoyte should have specific expertise with polypropylene.

An expert may be qualified by "knowledge, skill, experience, training, or education[.]" Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). Dr. Hoyte's clinical experience includes performing thousands of procedures involving female pelvic organ prolapse surgeries, including approximately one

hundred mesh revisions a year, and examining hundreds of patients with mesh complications. Based on his clinical and professional experiences, including his status as the Division & Fellowship Director of Female Pelvic Medicine and Reconstructive Surgery at the University of South Florida, Morsani College of Medicine, I **FIND** that Dr. Hoyte is qualified to offer his opinion that the mesh products in question do not shrink.

Next, Bard asserts that Dr. Hoyte's methodology is unreliable because he does not rely on sufficient facts or data. Specifically, Bard contends, "Dr. Hoyte's opinions are supported only by the Material Safety Data Sheet ("MSDS") for the raw [propylene] material, not the finished device, as well as his own general experience." Bard's Mem. in Supp., at 4-5. In response, the plaintiffs represent that the challenged opinions are not testimony Dr. Hoyte intends to offer, "but . . . are instead the evidentiary and factual predicate for his opinions." Notice of Adoption of Prior Daubert Resp. of Lennox Hoyte, M.D. For Waves 4 & 5 Cases, Ex. 1 ("Pls.' Resp.") at 3-4 [ECF No. 4596-1].

Given the plaintiffs' concession that Dr. Hoyte does not intend to opine on these issues, Bard effectively challenges the admissibility of certain evidence rather than the admissibility of Dr. Hoyte's opinions. Accordingly, I will not address the motion on this point at this time. To the extent Bard believes Dr. Hoyte misinterprets the evidence or that he acknowledges a shift in opinion between writing his report and deposition, Bard is free to explore these perceived deficiencies on cross-examination. Therefore, Bard's motion on this point is **DENIED**.

B. Opinions Regarding Product Design and Sufficiency of Studies

Bard also argues that Dr. Hoyte is not qualified to opine on the design of Avaulta mesh because: (1) he has no training or formal education pertaining to mesh pore size; (2) he has never designed a mesh product; (3) he has never tested porcine to evaluate "the likelihood of an intense inflammatory reaction"; and (4) he has never implanted an Avaulta device in a live patient. *See* Bard's Mem. in Supp., at 7-8.

Previously, in *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 624-25 (S.D. W. Va. 2013), I stated that it was "clear that Dr. Hoyte is qualified by knowledge, skill, experience, training, or education to opine as to the design of Avaulta mesh products." *Id.* (quoting Fed. R. Evid. 702). While Bard acknowledges my prior holding, it claims that "Dr. Hoyte's report identifies a variety of new alleged shortcomings in the design of Bard's devices." Bard's Mem. in Supp., at 6. I disagree.

To the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. Because my prior reasoning and conclusions still govern, I **ADOPT** the reasoning articulated in *In re C. R. Bard, Inc.*, and **FIND** that Dr. Hoyte is qualified to offer expert testimony regarding product design. Bard's motion is **DENIED** on this point.

Bard also takes issue with Dr. Hoyte's qualifications to opine on the sufficiency of Bard's testing. On this particular issue, absent greater context, I am without sufficient information at this time to draw the fine line between qualified and unqualified expert testimony on the adequacy of product testing. Accordingly, I **RESERVE** ruling on the admissibility of this testimony for trial.

C. Opinions Regarding Specific Plaintiffs

As noted above, the instant motion pending before the court is presented as a "Notice," wherein Bard adopts and incorporates by reference the *Daubert* motion and its corresponding documents filed in a previous case. As a result, certain aspects of this reinstituted motion are irrelevant to Bard Wave 4 or Wave 5 cases, such as testimony pertaining to specific plaintiffs situated in prior waves. Therefore, Bard's motion on the admissibility of Dr. Hoyte's opinions regarding specific plaintiffs is **DENIED as moot**.

D. Expert Opinions Cast as Legal Opinions

Bard also wishes to exclude Dr. Hoyte's opinion that "Bard failed to adequately warn physicians and patients" because it constitutes an improper legal conclusion. Bard's Mem. in Supp., at 9 (quoting Notice of Adoption of Mot. to Exclude or Limit Certain Ops. & Test. By Lennox Hoyte, M.D. in Wave 4 & Wave 5 Cases, Ex. B ("Dr. Hoyte's Expert Report"), at 9). Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008). Thus, to the extent

that Dr. Hoyte's opinions constitute legal conclusions, those opinions are **EXCLUDED**. Bard's motion is **GRANTED** on this point.

E. FDA Regulatory Requirements

According to Bard, Dr. Hoyte opines on the purpose of FDA labeling requirements and the ways in which Bard allegedly failed to fulfil those requirements. I agree that this testimony is inadmissible. This case concerns state tort law, not federal regulatory law, and as such, a recap of an FDA panel's findings will not "help the trier of fact to understand the evidence or to determine a fact in issue," Fed. R. Evid. 702. Indeed, discussion of the FDA panel's position through an expert witness could lead to more confusion than enlightenment. The jurors may erroneously believe that the FDA's "stance" relates to the validity of the plaintiffs' state law tort claims, or they may attach undue significance to the FDA panel's determination. Therefore, finding the probative value of this testimony to be substantially outweighed by the risk of misleading the jury, I **EXCLUDE** Dr. Hoyte's opinions and testimony related to the FDA. *See* Fed. R. Evid. 403; *see also Daubert*, 509 U.S. at 595 (emphasizing that courts must keep the other evidentiary rules in mind when evaluating the admissibility of expert opinions because expert evidence can be "both powerful and quite misleading"). Bard's motion on this point is therefore **GRANTED**.

F. Product Labeling Opinions

According to Bard, Dr. Hoyte is not qualified to offer expert testimony on the adequacy of the mesh product's IFU because he has no specialized knowledge of IFUs beyond his experience as a physician.

Although Dr. Hoyte has no experience with drafting IFUs, he has demonstrated experience in female pelvic medicine and the risks associated with the use of the mesh products in question. Based on his experience, I find him qualified to testify about whether the risks he perceives are in fact warned about in the IFU. Dr. Hoyte's opinion testimony on the IFU must stop here, however. A doctor who has no background in the requirements of an IFU is not qualified to opine that it "adequately and appropriately" warns of the risks merely because he personally knows about or has observed risks in his practice. *See, e.g.*, *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 584 (S.D. W. Va. 2014) (excluding a urologist as unqualified to opine that a DFU "adequately warned" of "all [] potential complications"). Accordingly, without additional expertise in the specific area of product warnings, these opinions on the IFU are **EXCLUDED**. Bard's Motion on this point is thus **DENIED in part** and **GRANTED in part**.

G. Opinions on Bard's Knowledge, Conduct, or State of Mind

Finally, Bard argues that I should preclude Dr. Hoyte from testifying as to its knowledge or state of mind. I agree; experts may not testify about what other parties did or did not know. However, to the extent Bard seeks to exclude Dr. Hoyte's testimony about factual issues or the knowledge of the medical community in general, I disagree. Expert witnesses may properly offer opinions on these topics. Therefore,

the motion is **GRANTED** to the extent that it seeks to exclude evidence regarding Bard's knowledge or intent.

IV. Conclusion

For the reasons stated above, the court **ORDERS** that the Notice of Adoption of Motion to Exclude or Limit Certain Opinions and Testimony by Lennox Hoyte, M.D. in Wave 4 and 5 cases [ECF No. 4569], which has been construed by this court as a Motion, is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 5, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.